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(71) Applicant (for all designated States except US): INNOVATIVA BIOMED LIMITED [GB/GB]; The Ziggurat, 25 Grosvenor Road, St. Albans AL1 3HW (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): BRAITHWAITE, Philip [GB/GB]; ML Laboratories Plc, 13 Alexandra Way, Ashchurch Industrial Estate, Tewkesbury GL20 8NB (GB).

(74) Agent: FOOTE, Harrison, Goddard; Tower House, Merrion Way, Leeds LS2 8PA (GB).

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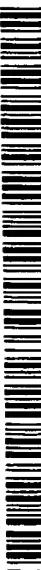
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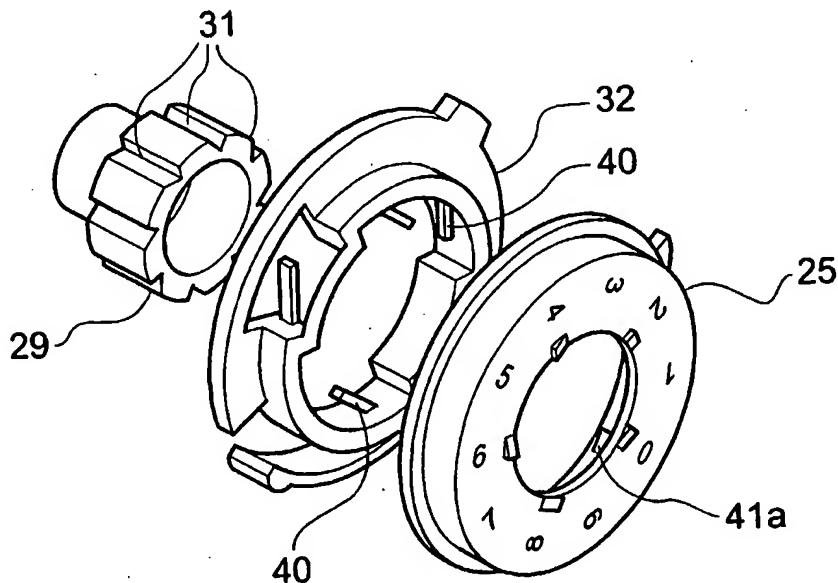
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(54) Title: MECHANICAL DOSES COUNTER IN A POWDER INHALER



WO 01/31578 A1



(57) Abstract: There is described a counter mechanism which comprises a rotatable ratchet adapted to act on a drive gear, the ratchet also acting on a counter wheel, characterised in that the rotation of the counter wheel is less than the rotation of the drive gear. There is also described a medicament delivery device, e.g. an inhaler comprising the counter mechanism of the invention and also a method of treatment using the delivery device.

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## MECHANICAL DOSES COUNTER IN A POWDER INHALER

This invention relates to a novel form of counter mechanism and particularly to a medicament delivery device comprising the mechanism.

5

In a particular embodiment of the invention the medicament delivery device comprises an inhaler, such as, a dry powder inhaler which is adapted to provide increased dosages of medicament.

10 Dry powder inhalers are known, such as CLICKHALER, produced by Innovata Biomed in the UK. Such a device is described in European Patent No 0 539 469.

15 Such inhalers generally comprise a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage.

20 The metering member described in European Patent No 0 539 469 is a frusto conical member comprising a side wall containing ten measuring chambers. The metering member is rotatable from an operable to an inoperable position. Thus, in the operable position, the position of one of the measuring chambers corresponds with an aperture in the medicament reservoir, whilst in the inoperable position the frusto conical side wall of the metering member corresponds with the aperture in the medicament reservoir thus providing a seal. The metering member is generally actuated, that is, moved from an inoperable to an operable position, by the patient depressing an actuator button which in turn engages with a ratchet, the ratchet then acts on the metering member via a gear member attached to an integral counter member.

30 There has long been a desire to increase the capacity of the measuring chamber without changing the overall shape of the cone. However, the current cone used in

the commercially available CLICKHALER is provided with ten measuring chambers which is ideally suited for use in a decimal dosage counter. By increasing the size of measuring, but retaining the shape of the cone, the number of measuring chambers is reduced to eight. This clearly presents a problem when such an arrangement is 5 coupled to a decimal; counter mechanism. This problem has thus far prevented the development of dry powder inhalers as hereinbefore described which poses greater dosage delivery capacity.

10 However, we have now found a novel counter mechanism that enables a greater measuring member capacity to be achieved, in general terms, by the use of a novel gear/counter and ratchet mechanism in combination whilst retaining the 75° cone.

15 Thus according to the invention we provide a counter mechanism which comprises a rotatable ratchet adapted to act on a drive gear, the ratchet also acting on a non-integral counter wheel, wherein the rotation of the counter wheel is less than the rotation of the drive gear.

20 More especially we provide a counter mechanism as hereinbefore described wherein the rotatable ratchet is adapted to act on a drive gear to rotate it through 45°, the ratchet also acting at the same time on a counter wheel to rotate it through 36°.

25 The counter mechanism preferably comprises a rotatable ratchet provided with one or more inner facing pawls and one or more outer facing pawls, said inner facing pawls are adapted to act on the drive gear, the drive gear being provided with eight evenly spaced external circumferential members, e.g. grooves, for engaging with said inner facing pawl(s) and said outer facing pawls adapted to act on the counter mechanism, the counter member being provided with ten evenly spaced inner circumferential members, e.g. shoulders, for engaging with the outer facing pawl(s)

30 The counter mechanism hereinbefore described is especially advantageous for use in counting the dispensing of medicament. Thus the counter is especially suitable for

use in connection with a medicament delivery device. Such a medicament delivery device may be an inhaler and especially a dry powder inhaler (DPI).

Therefore, according to a further feature of the invention we provide an inhaler 5 comprising a medicament reservoir, an inhalation passage for delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member comprising a frusto conical member provided with a plurality of measuring chambers characterised in that the metering member is actuated by rotation of a 10 ratchet acting on a drive gear, the ratchet also acting on a counter wheel and wherein the rotations of the counter wheel is less than the rotation of the drive gear.

In a preferred embodiment the inhaler is a DPI. Thus in a DPI such as a CLICKHALER, this arrangement enables conventional components, currently used 15 in a ten chamber inhaler, to be utilised in an eight chamber inhaler without any loss of accuracy in the dosage counting displayed to the patient.

In the prior art device described in European Patent No 0 539 469 the ratchet is provided with a nipple which engages with a recess in an actuator. However, we 20 have found that improved actuation, delivering larger dosages of medicament, can be achieved if the actuator is provided with a nipple and the ratchet provided with means for receiving the nipple, e.g. a recess.

The ratchet and gear system is preferably a multicomponent system comprising an 25 inner drive gear and an outer ratchet. In the prior art device the ratchet acts on gear wheel which includes an integral counter mechanism. However, in the present invention in order that the degrees of rotation of the counter member and the ratchet can differ from one another the ratchet is also provided with means for engaging with a drive gear wheel, said first gear wheel being separate from the counter member. 30 The engagement means may be any means conventionally known. However, it is preferred that the engagement means comprises a resilient member, e.g. a resilient

pawl and preferably comprises a plurality of such resilient members. Thus a plurality of gear engagement means are situated about the inner circumferential surface of the ratchet. Such engagement means preferably comprise a plurality of pawls, such pawls being of a resilient plastics material.

5

The external circumferential surface of the ratchet is also provided with means of engaging an outer counter, which counter is designed to increase in increments of ten. Such outer counter engagement means will generally comprise a pawl e.g. a resilient pawl, adapted to engage a notch on the outer counter. In an especially preferred 10 embodiment the inner counter is also provided with a pawl such that when the inner counter reaches a given number then the outer counter is actuated.

Conventional counter mechanisms comprise ascending incremental counters, that is a counter which indicates the number of dosages taken. The preferred counter of the 15 present invention is a decremental counter, that is a counter which counts the number of dosages remaining for ease of use by the patient. Even though the metering member is provided with only eight measuring chambers, it is desirable that the inner counter counts to ten before the patient sees a change in the outer counter. This is achieved by providing the inner counter with two circumferential cams, each 20 separately adapted to act on the outer counter. The underside of the outer counter is provided with corresponding recesses adapted to engage with each cam in turn.

A variety of medicaments may be administered by using the inhaler of the invention. Such medicaments are generally (but not limiting) antibiotics, bronchodilators or 25 other anti-asthma drugs. Such medicaments include, but are not limited to  $\beta_2$ -agonists, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. 30 sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g.

nedocromil sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.

Specific combinations of medicaments which may be mentioned include 5 combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of to  $\beta_2$ -agonists, such as, formoterol and salmeterol. It is also within the scope of this invention to include combinations of one or more of the aforementioned steroids with one or more of the aforementioned  $\beta_2$ -agonists.

10

Further medicaments which may be mentioned include systemically active materials, such as, proteinaceous compounds and/or macromolecules, for example, hormones and mediators, such as insulin, human growth hormone, leuprolide and alpha interferon; growth factors, anticoagulants, immunomodulators, cytokines and nucleic 15 acids.

According to a yet further feature of the invention we provide a method of administering a dry powder medicament using a delivery device as hereinbefore described.

20

By the term dry powder we mean a medicament in finely divided form.

The method of the invention may, optionally, include the administration of a combination of medicaments.

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We further provide a method of treatment of a patient with a disorder comprising the administration of a therapeutically effective amount of a medicament using a medicament delivery device according to the invention. We especially provide a method of treatment of a patient with a respiratory disorder comprising the 30 administration of a therapeutically effective amount of a medicament using an inhaler as hereinbefore described.

The invention will now be described by way of example only and with reference to the accompanying drawings in which:

5 Figure 1 is a schematic representation of an inhalation device not of the invention;

Figure 2 is an analogous schematic representation of an inhalation device of this invention;

10 Figure 3 is a perspective view of a disassembled inhalation device of the invention;

Figure 4 is a schematic dose counter diagram;

Figure 5 is a perspective drawing of the ratchet drive gear and counter wheel of the invention;

15 Figure 6 is a cross-sectional schematic representation of the ratchet, drive gear and counter wheel of the invention;

Figure 7 is a cross-sectional schematic representation of the ratchet, drive gear and counter wheel in operation;

Figure 8 is a cross-sectional schematic representation of the mechanism of the invention showing the counter wheel in place; and

20 Figure 9 is a cross-sectional schematic representation of a decremental counter using the mechanism of the invention.

With reference to Fig 1 of the prior art, an inhalation device (1) comprises a medicament reservoir (2) and plug (3), and a metering member support (4), an inhalation passage (5) and a waste box (6). A metering member (7) comprises a frustoconical 75° cone provide with ten measuring chambers (8). An inner counter and gear (9) is provided with a circumferential cam (10) and a pentagonal spindle socket (11) (spindle not shown). The underside of the counter (not shown) is provided with a plurality of notches (not shown) about the spindle socket (11).

30 A ratchet (12) is provided with nipple (13) for engaging with an actuator (not shown) and an outer circumferential resilient cam member (14). The ratchet (12) is provided

on its inner surface with a plurality of circumferential pawls (15) which are adapted to secure with the counter (9) and with a plurality of protrusions (16) adapted to engage with the notches of the counter (9).

With reference to Fig 2 of the invention, an inhalation device (17) comprises a medicament reservoir (18) and plug (19), and a metering member support (20), an inhalation passage (21) and a waste box (22). A metering member (23) comprises a frustoconical 75° cone provide with eight measuring chambers (24). An inner counter (25) is provided with two outer circumferential cams (26 and 27) and a separate gear cog (29) which cog is provided with 8 teeth (30) and recesses (31) adapted to be engaged by a ratchet (32). The ratchet (32) is provided with circumferential pawls (40) and an outer circumferential resilient cam member (41). The cog (29) is provided with a central aperture (33) adapted to engage with the spindle (not shown). The ratchet (32) is provided with a circumferential recess (34) adapted to be engaged by a nipple situated on an actuator (not shown).

With reference to Fig 3 of the invention, an inhalation device (17) comprises a medicament reservoir (18) and plug (19), and a metering member support (20), an inhalation passage (21) and a waste box (22). A mouthpiece (35) is also shown. A metering member (23) comprises a frustoconical 75° cone provide with eight measuring chambers (24). An inner counter (25) is provided with two outer circumferential cams (26 and 27) and a separate gear cog (29) which cog is provided with 8 teeth (30) and recesses (31) adapted to be engaged by a ratchet (32). The ratchet is biased towards the gear by spring (36). The cog (29) is provided with a central aperture (33) adapted to engage with the spindle (not shown). The ratchet (32) is provided with a circumferential recess (34) adapted to be engaged by a nipple situated on an actuator (not shown). There is also shown an outer counter (37), the inner counter (25) being provided with five ratchet stops (38). A back plate (39) is also shown.

With reference to figures 5 and 6 of the counter mechanism of the invention comprises a drive gear (29), a ratchet (32) and a counter member (25). The drive gear is provided with recesses (31) adapted to engage with inner circumferential

pawls (40) of the ratchet (32). The recesses (31) are placed 45° apart around the circumference of the drive gear (29). The inner surface (41a) of the counter (25) is provided with circumferential teeth (41) adapted to engage with the outer pawl (34) of the ratchet (32). The inner circumferential teeth (41) are spaced 36° apart.

- 5 Referring to figures 7a-d, 3° of travel exists at point x between the pawl (40) of the ratchet (32) and the recess (31) of the drive gear (29). Thus, during one actuation, the ratchet (32) will actually rotate 48°. Referring to figure 7b), the ratchet (32) initially rotates 3° and makes contact with the drive gear (29). Referring to figure 7c), once the ratchet (32) has rotated 12°, the outer circumferential pawl (34) makes contact
- 10 with the tooth (41) of the counter member (25). Referring to figure 7d), when the actuation is complete, the ratchet (32) and drive gear (29) have moved through 45° and the counter member (25) has moved through 36°. The ratchet (32) is released and returns by rotating clockwise, the outer pawl (34) passing over the next tooth (41a) in a clockwise direction and the inner pawl (40) passing over the next recess (31a).
- 15

Referring to figure 8, upon each full rotation of the counter member (25), i.e. every ten actuations, the circumferential cam (26) of the counter member (25) urges the cam (14) of the ratchet against the inner surface (42) of the outer counter (37). The inner surface (42) is provided with ridges (43) against which the cam (14) is urged, causing the outer counter (37) to move to count an increment of ten.

- 20

Referring to figure 9, a decremental counter may be provided by the use of a pair of circumferential cams (26 and 27) on the outer surface of the inner counter (25). Thus in operation the inner counter (25) counts to ten before the patient sees a change in the outer counter (37). The first outer cam (26) acts on the cam (14) of the ratchet (32) to urge it against the inner surface (42) of the outer counter (37) to rotate the outer counter (37). However, because each numeral is duplicated, the patient will not see a change in the outer counter until the next actuation and the second cam (27) acts on the cam (14) of the ratchet (32) to urge it against the inner surface (42) of the outer counter (37) to rotate the outer counter (37).

- 25

**CLAIMS**

1. A counter mechanism which comprises a rotatable ratchet adapted to act on a drive gear, the ratchet also acting on a counter wheel, wherein the rotation of the counter wheel is less than the rotation of the drive gear.  
5
2. A counter mechanism according to Claim 1 characterised in that the rotatable ratchet is adapted to act on a drive gear to rotate it through 45°, the ratchet also acting at the same time on the counter wheel to rotate it through 36°.  
10
3. A counter mechanism according to Claim 1 comprising a rotatable ratchet provided with one or more inner facing pawls and one or more outer facing pawls, said inner facing pawls are adapted to act on the drive gear, the drive gear being provided with eight evenly spaced external circumferential members for engaging with said inner facing pawl(s) and said outer facing pawls adapted to act on the counter mechanism, the counter member being provided with ten evenly spaced inner circumferential members, e.g. shoulders, for engaging with the outer facing pawl(s)  
15
4. A counter mechanism according to Claim 1 that is a decremental counter.  
20
5. A counter mechanism according to Claim 4 characterised in that the inner counter is provided with two circumferential pawls, each separately adapted to act on the outer counter.  
25
6. A counter mechanism according to Claim 5 characterised in that the underside of the outer counter is provided with corresponding recesses adapted to engage with each pawl.  
30
7. A medicament delivery device comprising a counter mechanism according to claim 1.

8. A medicament delivery device according to claim 7 characterised in that the device is an inhaler.
- 5 9. A medicament delivery device according to claim 8 characterised in that the inhaler is a dry powder inhaler.
10. A medicament delivery device according to claim 7 characterised in that the inhaler comprises a medicament reservoir, an inhalation passage for delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member comprising a frusto conical member provided with a plurality of measuring chambers characterised in that the metering member is actuated by rotation of a ratchet acting on a drive gear, the ratchet also acting on a counter wheel and wherein the rotations of the counter wheel is less than the rotation of the drive gear.
15. 11. A medicament delivery device according to Claim 10 characterised in that the ratchet is provided with means for receiving a nipple from an actuator.
20. 12. A medicament delivery device according to Claim 10 characterised in that the ratchet is provided with means for engaging with a drive gear, said drive gear being separate from the counter member.
25. 13. A medicament delivery device according to Claim 10 characterised in that the ratchet is provided with means for engaging with a drive gear, said drive gear being separate from the counter member.
30. 14. A medicament delivery device according to Claim 10 characterised in that the engagement means comprises a resilient pawl.

15. A medicament delivery device according to Claim 14 characterised in that the engagement means comprises a plurality of resilient pawls.
16. A medicament delivery device according to Claim 10 characterised in that the external circumferential surface of the ratchet is also provided with means of engaging an inner counter and means for engaging an outer counter.
17. A medicament delivery device according to Claim 16 characterised in that the outer counter is a decremental counter.
18. A medicament delivery device according to Claim 15 characterised in that the inner counter is also provided with a pawl such that when the inner counter reaches a given number then the outer counter is actuated.
19. A method of administering a dry powder medicament using a delivery device according to Claim 7.
20. A method according to claim 19 characterised in that a combination of medicaments are administered.
21. A method of treatment of a patient with a disorder comprising the administration of a therapeutically effective amount of a medicament using a medicament delivery device according to claim 7.
22. A method of treatment of a patient with a respiratory disorder comprising the administration of a therapeutically effective amount of a medicament using an inhaler according to claim 8.
23. A counter mechanism or a delivery device substantially as described with reference to the accompanying drawings.

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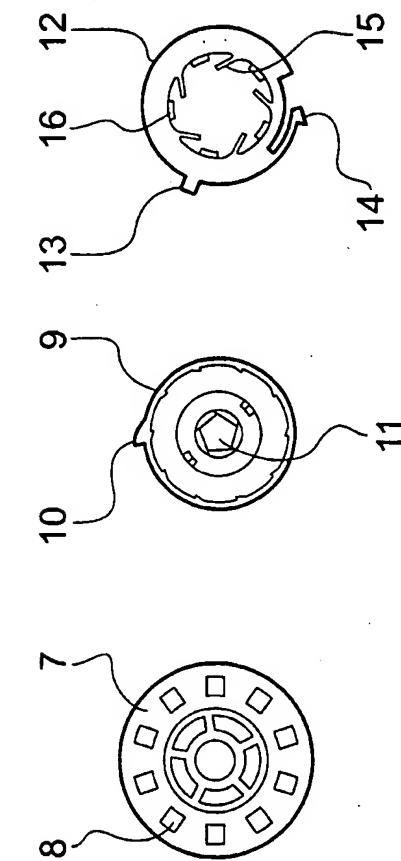


Fig. 1

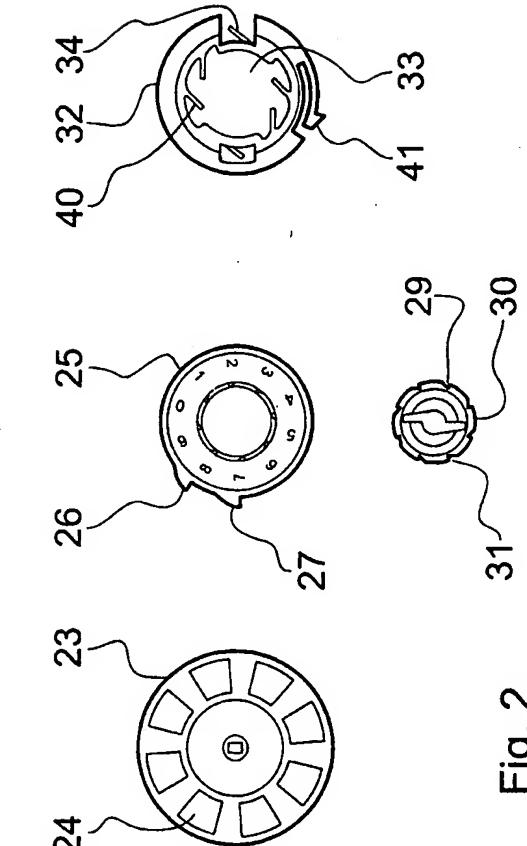
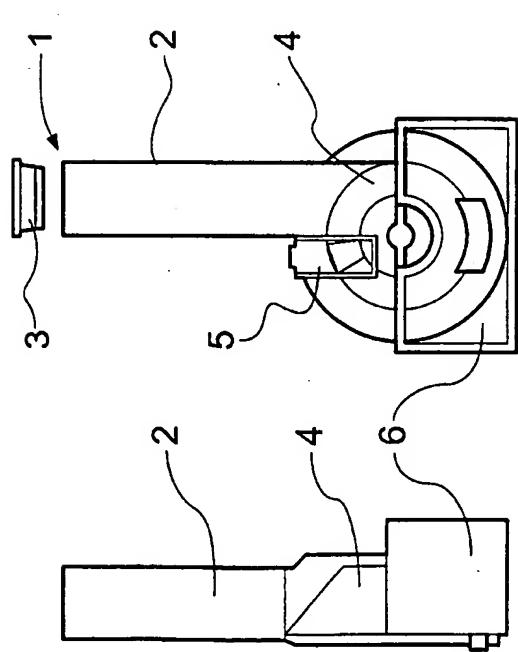
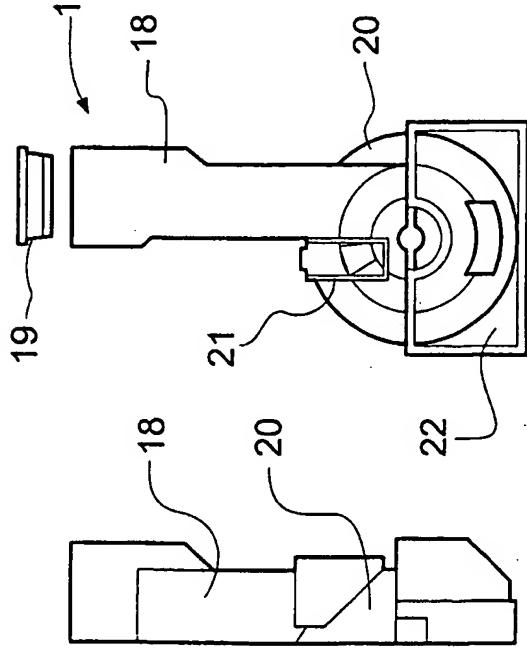


Fig. 2



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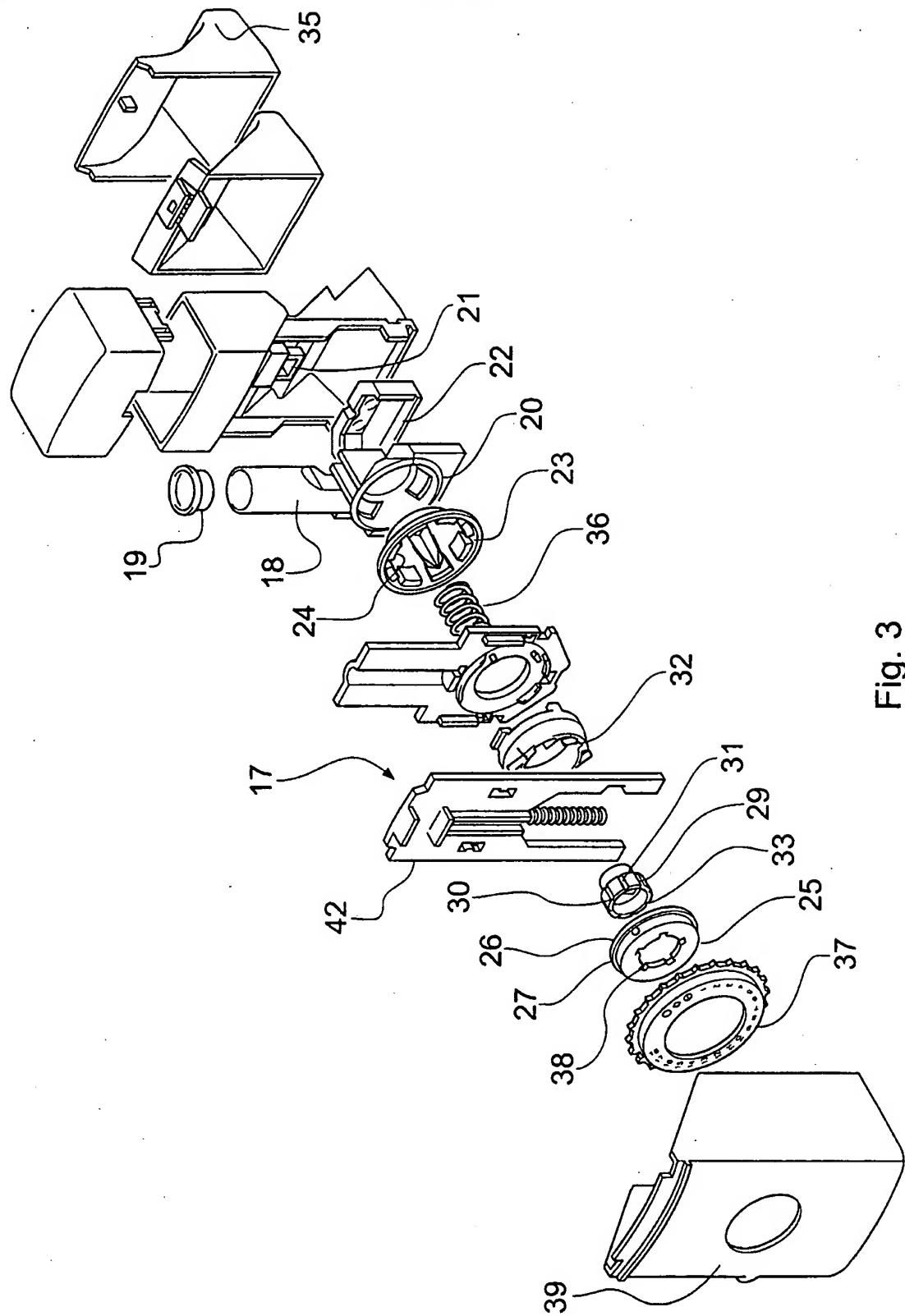


Fig. 3

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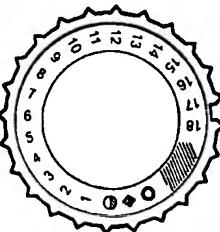
Incremental Counter 200 Doses	Decremental Counter 80 Doses
Assembly / Inspection 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 10 11 12	3 2 1 0 9 8 7 6 5 4 3 2 1 0 9 8 7 6 5 4 3 2 1 0
Filler & then User 0 1 2 3 4 5 6 7 8 9 0 1 10 11 12	Change 0
	Device Empty: Push Button Locked 0
<b>Current Dose Counter</b>  <b>New Dose Counter Components</b> 	

Fig. 4

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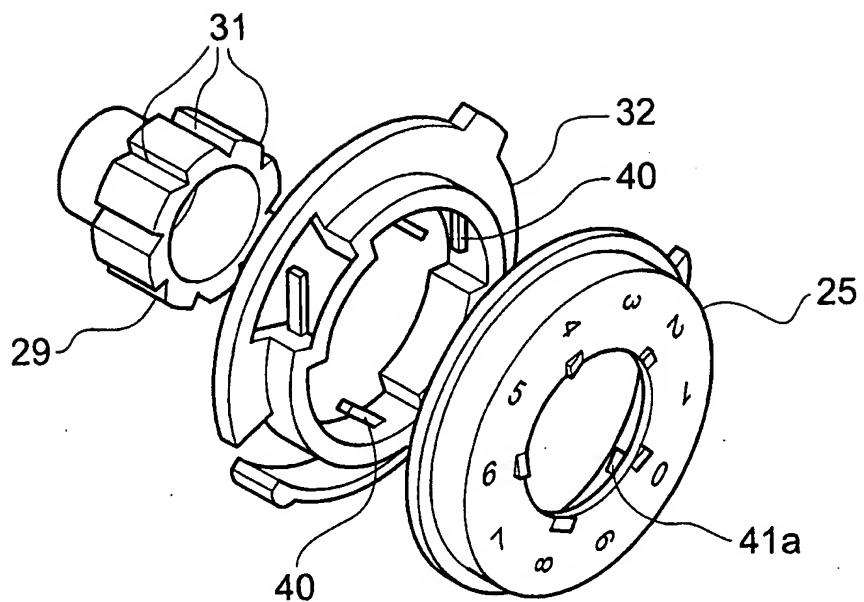


Fig. 5

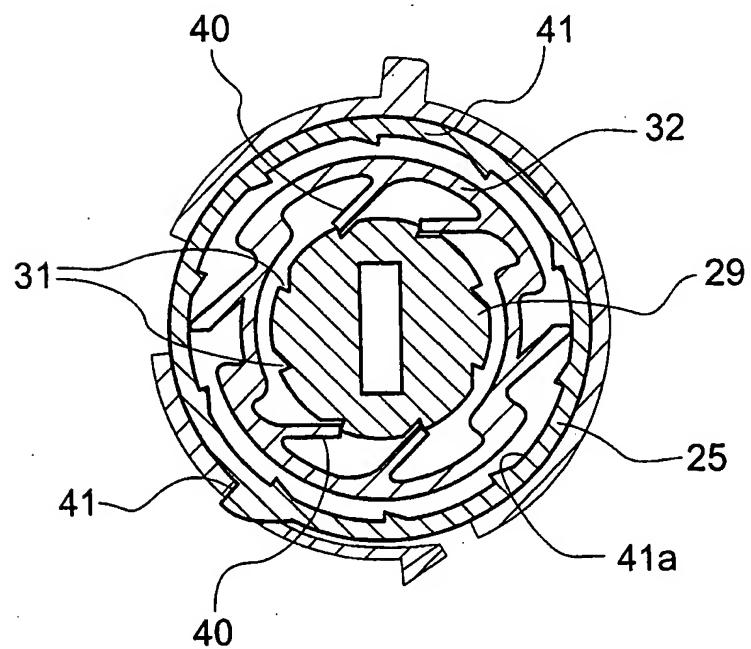


Fig. 6

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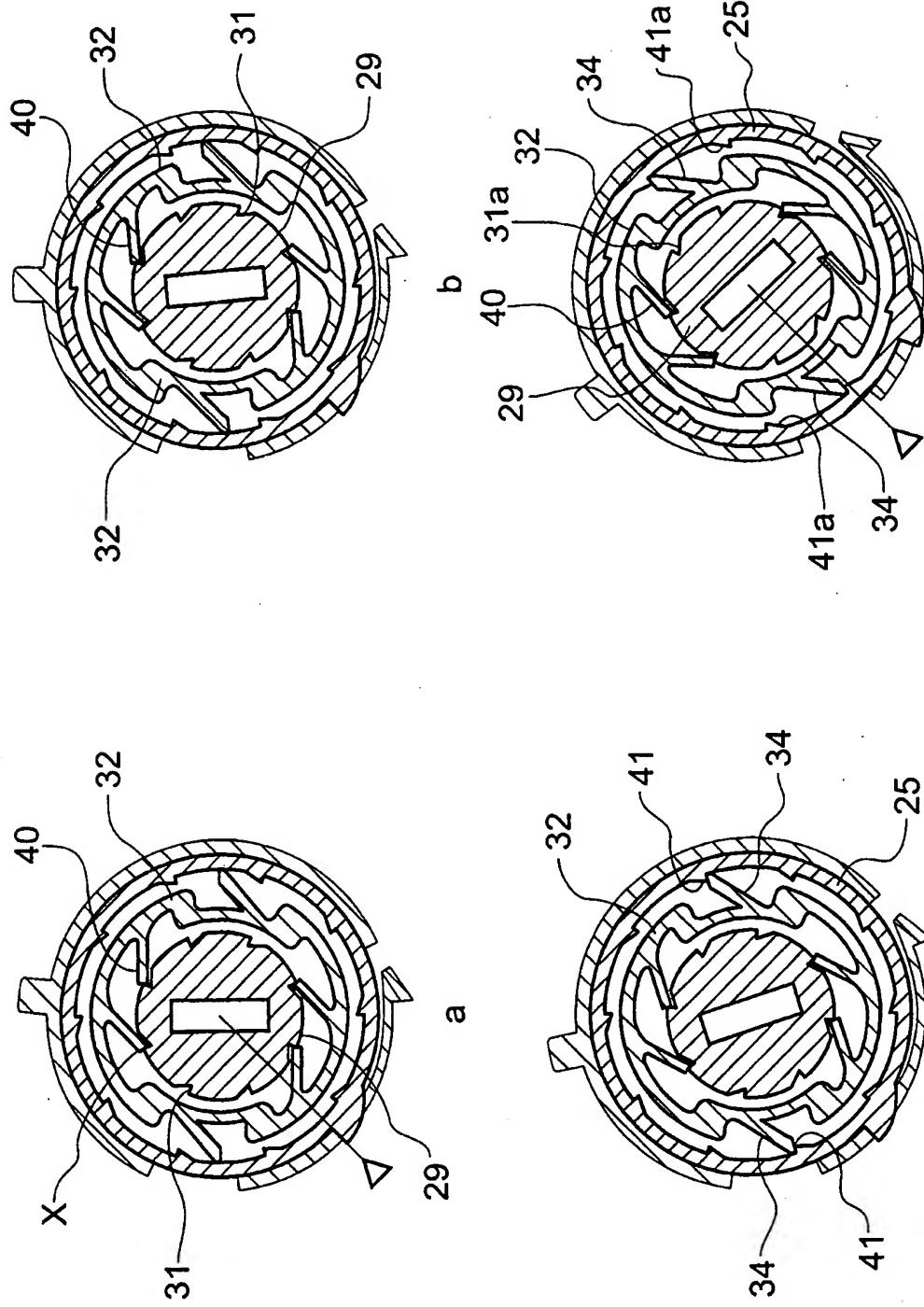


Fig. 7

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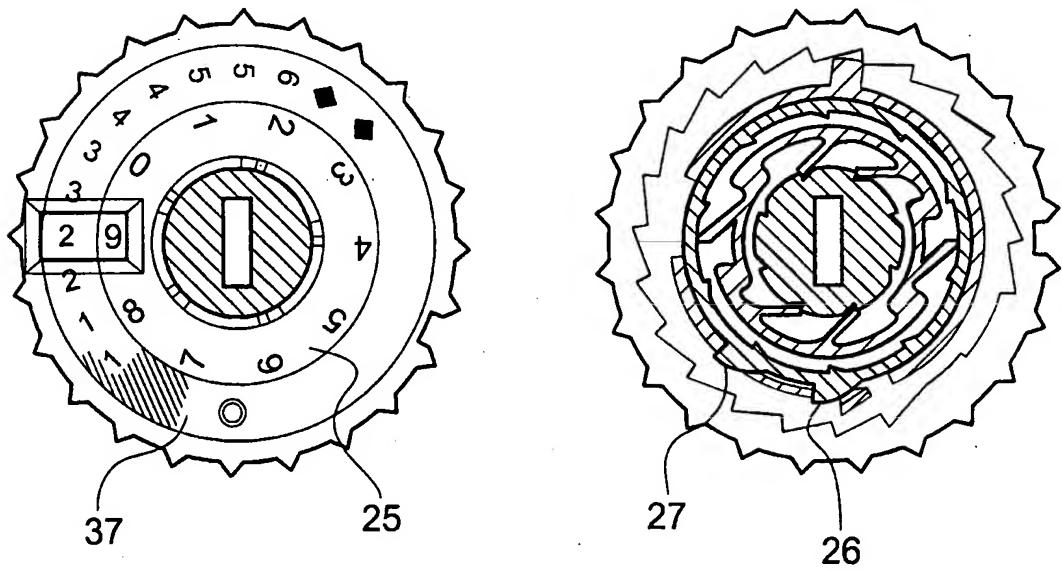
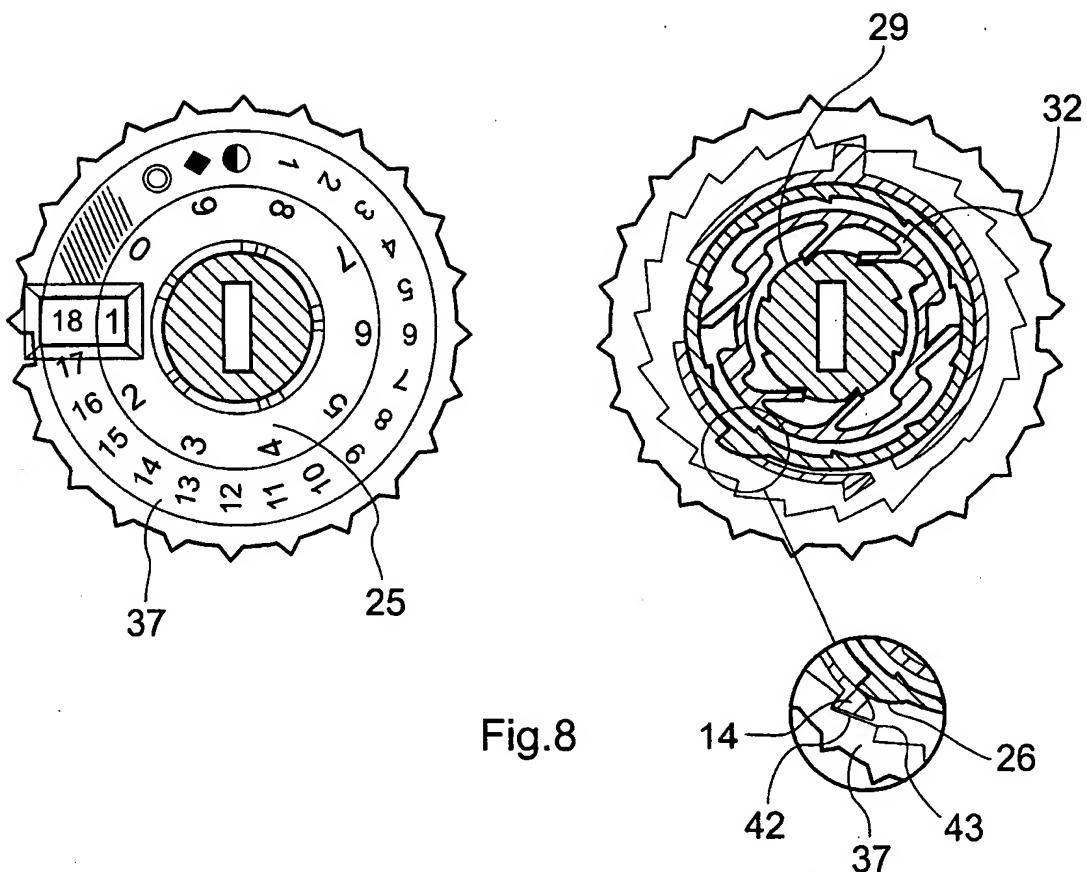


Fig. 9

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/04045

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 G06M1/04 G06M1/08

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 G06M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 92 00771 A (INNOVATA BIOMED LTD)    23 January 1992 (1992-01-23)    cited in the application    page 3, line 15 -page 7, line 22    page 12, line 32 -page 13, line 18;    figures</p> <p>-----</p>	1-23



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents :

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Date of the actual completion of the international search

1 February 2001

Date of mailing of the international search report

09/02/2001

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

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